

### REMARKS

This document is filed in reply to the Office Action dated December 31, 2007 ("Office Action"). Applicants have amended claims 1, 5, 12, and 29 to more clearly set forth the claimed invention. At the Examiner's suggestion, claim 5 is rewritten in independent form, support for which can be found in the specification at, e.g., page 1, lines 17-22. Support for the amendment to claim 12 appears in, e.g., original claim 8. Support for the amendment to claim 29 can be found at, e.g., page 1, lines 17-22 of the specification. Claims 11 and 18 are cancelled. The specification is amended to specify trademarks at the Examiner's request. No new matter is introduced.

Upon entry of the proposed amendments, claims 1-3, 5-10, 12-17, and 19-29 will be pending. Among them, claims 2, 3, 6, 7, 9-10, 13-17, and 19-28 have been withdrawn from further consideration for covering a non-elected invention. Claims 1, 5, 8, 12, and 29 will be under examination. Reconsideration of this application is requested in view of the following remarks.

#### 35 U.S.C. § 112 Second Paragraph Rejection

Claim 29 was rejected for indefiniteness. See the Office Action, page 3, lines 1-3. In view of the above amendment to claim 29, Applicants request that the rejection be withdrawn.

#### 35 U.S.C. § 112 First Paragraph Rejections

Claims 1, 8, and 29 were rejected as failing to comply with the written description requirement. See the Office Action, page 4, lines 1-2. According to the Office Action,

Claims 1, 8, and 29 are drawn to polypeptides comprising the enzymatic catalytic domain (SEQ ID NO[s]: 3 and 4) of 1,3-1,4- $\beta$ -D-glucanase of SEQ ID NO: 1 and excluding 78 carboxyl amino acid of SEQ ID NO: 1 ... Such polypeptides can comprise of amino acids 1-266 and amino acid 267, 268, 269, 270, and/or 271. However, ... The specification as filed contains disclosure of only a truncated polypeptide of SEQ ID NO: 1 consisting of amino acids 24 to 271 of SEQ ID NO: 1.

See page 4, paragraph 2.

Applicants respectfully traverse. It is established that, when determining whether a specification is in compliance with the written description requirement, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed, and that the subject matter of the claim need not be described literally (i.e., using the same terms or in *haec verba*) in order for the disclosure to satisfy the description requirement. See MPEP 2163.02 (emphasis added). Also, a claim language does not have to be set forth verbatim in the specification. In *In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989), the Federal Circuit, in reversing a Board's 35 U.S.C. § 112, first paragraph rejection, held that there was adequate written description support for applicant's claim limitation, despite the fact that it was not set forth "*in haec verba*" in the specification.

As acknowledged by the Examiner, the claims at issue "are drawn to polypeptides comprising the enzymatic catalytic domain (SEQ ID NO[s]: 3 and 4) of 1,3-1,4- $\beta$ -D-glucanase of SEQ ID NO: 1 and excluding 78 carboxyl amino acid of SEQ ID NO: 1." The two catalytic domains, SEQ ID NOs: 3 and 4, correspond to aa 28-266 of SEQ ID NO: 1; the excluded 78 carboxyl amino acids correspond to aa 272-349 of SEQ ID NO: 1 (i.e., SEQ ID NO: 5). See page 3, lines 48-50 of the specification. It follows that the claimed polypeptides must (1) include aa 28-266 and (2) exclude aa 272-349 of SEQ ID NO: 1.

Further, the specification describes that catalytic domains can include extra amino acid(s) fuse to them. See page 3, lines 6-10. In view of the description, those skilled in the art could clearly appreciate that the extra amino acids fuse to the catalytic domains can be any amino acids. Also, in view of the relationship among SEQ ID NOs: 1, 3, 4, and 5 (i.e., SEQ ID NOs: 3-5 are within SEQ ID NO: 1 in order from the N to the C terminus), those skilled in the art could clearly appreciate that the first choice for the just-mentioned extra amino acids are those from aa 267 to aa 271 of SEQ ID NO: 1, all of which are explicitly disclosed in the specification. It is clear that these catalytic domains with fused extra amino acids were in possession of the invention and were clearly conveyed to those skilled in the art.

Thus, according to the above-cited guidance from MPEP and the Federal Circuit's opinion, there was adequate written description support for polypeptides comprising

“amino acids 1-266 and amino acid 267, 268, 269, 270, and/or 271,” despite the fact that some of them were not set forth “*in haec verba*” in the specification.

35 U.S.C. § 103 Rejections

Claims 1 and 8 were rejected as obvious over Teather *et al.* J. Bacteriology 172(7): 3837-3841 (“Teather”). See the Office Action, page 6, lines 1-2. Applicants disagree and will discuss independent claim 1 first.

Claim 1 is drawn to an isolated polypeptide having the enzymatic catalytic domains of a wild type 1,3-1,4- $\beta$ -D-glucanase sequence (SEQ ID NO: 1) and excluding the carboxyl terminal 78 amino acid residues of SEQ ID NO: 1. The isolated polypeptide has a higher enzymatic activity than the wild type 1,3-1,4- $\beta$ -D-glucanase.

According to the Examiner, Teather discloses that

five repeating sequence (PXSSS) [at the C terminus of *F. succinogenes* 1,3-1,4- $\beta$ -D-glucanase] ... may participate in stabilizing the active conformation of the protein but do not participate directly either in forming the substrate-binding site or in catalysis. ... [As such], it would be obvious to one having ordinary skill in the art ... to systematically delete amino acid residues at the C-terminal region of the 1,3-1,4- $\beta$ -D-glucanase of Teather *et al.*

See page 6, lines 9-19. Applicants respectfully traverse. According to MPEP 2143,

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

To support his prima facie case of obviousness, the Examiner asserted that “one of ordinary skill in the art would have been motivated to delete C-terminal amino acid in order to determine those sequences that are essential for enzymatic activity.” See page 6, lines 19-21, emphasis added.

Applicants disagree. Teather describes an *F. succinogenes* 1,3-1,4- $\beta$ -D-glucanase mutant, which was encoded by a nucleic acid having a “[d]eletion of the carboxy-terminal

region up to and including base 923.” See page 3838, right column, lines 51-64. In other words, the mutant contained aa 1-398 (encoded by nt 0-923) and lacked only the carboxy-terminal 41 amino acids of the total 349 amino acids. See FIG 1. This mutant had “about 0.16% of the original value” of the wild type enzyme activity and lost more than 99.8% of the activity, which is a 625-fold decrease.<sup>1</sup> See page 3838, line 54.

In view of this 625-fold decrease in enzymatic activity, one skilled in the art would have recognized that the carboxy-terminal 41 amino acids would contain “sequences that are essential for enzymatic activity.” If this “one of ordinary skill in the art” was motivated in the manner alleged by the Examiner, i.e., “to determine those sequences that are essential for enzymatic activity,” he or she would be motivated to determine sequences within the carboxy-terminal 41 amino acids, the loss of which resulted in a 625-fold decrease in the enzymatic activity. It follows that the one of ordinary skill in the art had no motivation to look at sequences outside the carboxy-terminal 41 amino acids, such as those deleted in the polypeptide of claim 1.

Thus, the Examiner has not met the first of the “three basic criteria” provided in MPEP 2143 so as to establish a prima facie case of obviousness.

The Examiner has not met the second of the “three basic criteria,” i.e., “there must be a reasonable expectation of success,” either. As mentioned above, the deletion of the carboxy-terminal 41 amino acids resulted in a 625-fold decrease in the enzymatic activity. Given a decrease of such a big magnitude, one of ordinary skill in the art would have no reasonable expectation of success of finding any “sequences that are essential for enzymatic activity” other than those in the carboxy-terminal 41 amino acids.

However, to support his prima facie case, the Examiner asserted that “[o]ne of ordinary skill in the art would have had a reasonable expectation of success since mutagenesis is a well known technique.” See page 7, line 21 to page 8, line 1. Applicants disagree. The mere fact that a technique is well known does not render an invention, which can be made by the technique, obvious. Indeed, the mere fact that typing words selected from a dictionary is a “well known technique” does not render a novel obvious over the

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<sup>1</sup> 625 = 100% ÷ 0.16%

dictionary. Likewise, the fact that “mutagenesis is a well known technique” does not render the polypeptide of claim 1 obvious. Thus, the Examiner’s assertion is not tenable.

Finally, the last of the three basic criteria requires that prior art reference (or references when combined) must teach or suggest all the claim limitations. As mentioned above, the isolated polypeptide of claim 1 must have an enzymatic activity higher than that of the wild type 1,3-1,4- $\beta$ -D-glucanase. In contrast, all of the mutants described in Teather have enzymatic activities substantially lower than that of the wild type 1,3-1,4- $\beta$ -D-glucanase. Thus, Teather does not provide the third required criterion.

Nonetheless, to rectify this defect, the Examiner alleged that the “property of having a higher enzymatic activity compared to the wild type enzyme would flow naturally upon deleting 78 C-terminal residues and therefore said property is inherent.,” See page 7, lines 1-4.

Applicants respectfully traverse and would like to bring to the Examiner’s attention that “[o]bviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993).” See MPEP 2141.02V. According to this section of MPEP:

In determining whether the invention as a whole would have been obvious under 35 U.S.C. 103, we must first delineate the invention as a whole. In delineating the invention as a whole, we look not only to the subject matter which is literally recited in the claim in question... but also to those properties of the subject matter which are inherent in the subject matter *and* are disclosed in the specification. . . . Just as we look to a chemical and its properties when we examine the obviousness of a composition of matter claim, it is this invention *as a whole*, and not some part of it, which must be obvious under 35 U.S.C. 103.” *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1977) ...

In *In re Antonie* cited above in MPEP 2141.02V, the Court of Customs and Patent Appeals reversed the Patent and Trademark Office Board of Appeals’ affirmation of an obviousness rejection based on an inherency theory. In *In re Antonie*, the invention at issue was a wastewater treatment device having a particular tank volume to contractor area ratio. Specifically,

The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The court found the invention as a whole was the ratio of 0.12 and its inherent property that the claimed devices maximized treatment capacity regardless of other variables in the devices. The prior art did not recognize that treatment capacity was a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.

See MPEP 2141.02V.

The polypeptide of claim 1 is analogous to the wastewater treatment device in *In re Antonie*. Like the wastewater treatment device, the polypeptide of claim 1 “as a whole was the [polypeptide with exclusion of the carboxyl terminal 78 amino acid residues of wild type 1,3-1,4-β-D-glucanase] and its inherent property that the claimed [polypeptide has an activity higher than that of the wild type 1,3-1,4-β-D-glucanase] regardless of other variables in the [polypeptide]. The prior art did not recognize that [higher activity] was a function of [exclusion of a certain region of the wild type enzyme], and therefore the [part excluded] was not recognized in the art to be a result-effective variable.” Accordingly, the Examiner’s reliance on inherency is as unteable as that of the Patent and Trademark Office Board of Appeals in *In re Antonie*.

In view of the above remarks, it is submitted that the Examiner has not met his burden to establish a *prima facie* case of obviousness a *prima facie*. Thus, the rejection should be withdrawn.

Even if a *prima facie* case of obviousness were established, which the Applicants do not agree, it can be successfully rebutted by a showing of an unexpected property of the claimed nucleic acid as compared with the closest polypeptides, i.e., those mutants described in Teather. Teather described three mutants. All of the mutants had enzymatic activities at least 625-fold lower than that of the wild type 1,3-1,4-β-D-glucanase. In contrast, it was unexpected that the isolated polypeptide of claim 1 has an enzymatic activity higher than that of the wild type 1,3-1,4-β-D-glucanase. This unexpected property clearly rebuts a *prima facie* case of obviousness relying on Teather.

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For the reasons and facts set forth above, Applicants submit that claim 1 is not obvious over Teather. Claim 8 depends from claim 1. For at least the same reason, it is also not obvious.

#### Allowable Subject Matter

The Examiner acknowledged that claims 5 and 12 would be allowable if rewritten in independent form. See the Office Action, page 7, lines 8-10. In the sole interest of moving this case forward, Applicants have rewritten claim 5 in independent form. In view of the amendments, Applicants request that claims 5 and 12 be allowed.

#### Conclusion

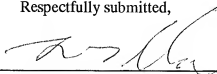
It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 70002-111001.

Respectfully submitted,

Date: \_\_\_\_\_

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